Message

From: Deener, Kathleen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B9A2FF1C086249EA8F6414AFDE8A5E54-DEENER, KATHLEEN]
Sent: 6/3/2011 1:57:24 PM
To: CN=Audrey Hoffer/OU=DC/O=USEPA/C=US@EPA
CC: Gatchett, Annette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f12d699a71f84e21bddbb876dae7f96c-Gatchett, Annette]; Clark, Becki [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a906e07f1cd143b9a3c2ddab813b8140-Clark, Becki]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; Barone, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4f8618acbba418da24c110f3123a2af-Barone, Stan]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Winner, Darrell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]
Subject: Re: IRIS press interview briefing
Attachments: HHRA Mid-Cycle Progress Report_June 22 2010_FINAL.pdf; HHRA Subcommittee Report-FINAL.pdf; BOSC HHRA Mid-Cycle Letter Report-FINAL.docx

Audrey - Here is some more text that might be helpful for this and other similar exercises. I've also attached a few documents you might find useful.

From the 2008 BOSC Review final report:

"IRIS also serves as the internationally recognized standard in chemical risk assessment for other federal, state, local, and international regulatory bodies, and the private sector. The comprehensiveness, transparency, and consistency of the IRIS approach have made it into the internationally recognized standard in hazard characterization. The IRIS Web site receives about 8 million visits annually, a testament to the value of IRIS as a resource."

"The HHRA Program has been highly responsive to the needs of the program offices and regions. The Subcommittee heard testimonials from a number of highly placed officials in regions and program offices who strongly value the work and expertise of the HHRA, both in providing risk assessment products (IRIS, PPRTVs, ISAs) and in supporting emergency responses to crises like the 9/11 terrorist attacks on the World Trade Center and Hurricane Katrina. Expertise in risk assessment within the HHRA Program has been critical in dealing with these and other disasters."

"The Subcommittee found that the HHRA Program makes extensive use of internal and external peer review to ensure that its outputs are of high quality. The extent of peer review for IRIS and ISA assessments exceeds most other examples with which the Subcommittee members were familiar. The review process appears to be effective."

And from the 2010 report from the BOSC in response to our Mid-Cycle Progress Report:

"The Executive Committee finds that the HHRA Program is a strong program whose output is crucial to much of the work of EPA's offices and regions."

"It also is noted that IRIS assessments and Integrated Science Assessments (ISA) are among the most heavily peer-reviewed documents produced by scientists anywhere. Although it is clear that good peer-review makes for better documents, it is not clear that all of the steps in the current process add value. EPA is encouraged to reach out to the Office of Management and Budget (OMB), and others if necessary (e.g., National Academies), to determine how much peer review is really needed and to identify the tipping point between a review that makes the report 1 percent better at the cost of postponing the release of a document that has real public health value, or which limits the number of reports that can be prepared."

Some text that might be used to describe setting priorities for IRIS:
The IRIS program meets regularly with EPA's Programs and Regions. In 2009, NCEA held multiple meetings with the programs and regions so we would better understand their regulatory and other needs for assessments for chemicals currently on the IRIS agenda. The purpose of this exercise was to help the HHRA Program set priorities for completing currently backlogged assessments. We will conduct a similar exercise to help us set priorities for newly nominated chemicals.

Administrator's memo on the new IRIS process:
http://www.epa.gov/iris/pdfs/IRIS_PROCESS_MEMO.5.21.09.PDF


HHRA Mid-Cycle Progress Report...


HHRA Subcommittee R...


BOSC HHRA Mid-Cycle Letter ...

Kacee Deener, MPH

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From: Lynn Flowers/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA
Cc: Becki Clark/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, winner.darrell@epa.gov
Date: 06/03/2011 08:41 AM
Subject: Re: IRIS press interview briefing

some additional comments in a few places (**underlined and some strikethrough**). I think that these are pretty good responses with all the additions that have been made.

From: Kathleen Deener/DC/USEPA/US
To: Becki Clark/DC/USEPA/US@EPA
Cc: Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, winner.darrell@epa.gov
Date: 06/02/2011 06:32 PM
Subject: Re: IRIS press interview briefing

A few thoughts (in red):

Q: How is OMB now involved in the IRIS process?

Deliberative Process / Ex. 5

Q:EPA announced updates to the IRIS process in May 2009 – what major changes to the program have been made since then? How has the process been streamlined and improved? Is the IRIS process now fully in EPA's hands? Why is this more effective? Has the agency had time to address the concerns raised in the April NAS report on EPA's formaldehyde assessment?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Q: That report prompted some industry stakeholders — notably the American Chemistry Council — and Sens. Inhofe and Vitter to criticize the transparency of the IRIS process. In an April letter from ACC chief Cal Dooley, the organization called on EPA to do more to discuss science as it reviews scientific information about how chemicals affect the body and more clearly explain why it relied on some scientific evidence more than others to reach conclusions about how the effects occurred.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Q: What is the agency's response to ACC's concerns and to its request the agency submit all draft IRIS assessments to the National Academies in 2011 and 2012?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Is the agency concerned about the large backlog of chemicals awaiting evaluation?

Deliberative Process / Ex. 5

Q: How is EPA trying to streamline the process for assessing chemicals and planning to analyze substances that might present future risks?

Deliberative Process / Ex. 5

Q: Has EPA begun trying to revamp the process to evaluate exposure to multiple chemicals?

Deliberative Process / Ex. 5

Q: Has the agency begun to consider assessing nanomaterials through IRIS? What new challenges might that pose for the agency?

Deliberative Process / Ex. 5

Excerpts from Vitter/Inhofe letter:

We are implementing the recommendations that the NAS panel offered in their review report. This includes specific revisions to more clearly describe the way in which the formaldehyde assessment was conducted and the basis for EPA's conclusions. It is important to note that many of the issues raised by the NAS are related to the presentation of the findings, not disagreements with specific scientific findings. It is also important to recognize that there are many key points on which the NAS agreed with the scientific conclusions in EPA's draft assessment. For example, the NAS agreed that "there is sufficient evidence . . . of a causal association between formaldehyde and cancers of the nose, nasal cavity, and nasopharynx," but recommended that EPA clarify the presentation of evidence and conclusions. The NAS also agreed with EPA's identification of the study and dataset from which to develop quantitative estimates of potential cancer risk. Additionally, the NAS agreed with EPA's conclusion regarding the link between formaldehyde exposure and pulmonary function, as well as with the selection of the main study for quantitative assessment of this endpoint.

Re: Overalll IRIS document development process. EPA will build on the existing guidelines and process to improve the clarity and transparency of the evaluation of the data, as well as the presentation of findings and conclusions, in future IRIS assessments. EPA plans to streamline the IRIS assessment documents while, at the same time, more fully documenting the systematic approach used by the EPA for assembling and evaluating the range of scientific data. As the NAS report indicates, we have already made similar changes to how we present the vast body of scientific evidence on the criteria air pollutants in the Integrated Science Assessments prepared pursuant to Section 108 of the Clean Air Act Amendments. We are confident that we can make comparable improvements in how we present our analysis of health study findings for chemicals evaluated for the IRIS program.

NAS recommended that the formaldehyde assessment and other IRIS assessments should not be put on hold, pending a revision of the IRIS presentation of results. Rather, the NAS stated "it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach." In accordance with advice from NAS, EPA intends to implement approaches for greater clarity in presentation for future IRIS assessments. Assessments that are already under development or are currently undergoing peer review will be evaluated to ensure that the rationale for study selection and evidence evaluation is clear.

The standards to which IRIS assessments are held, including the rigorous independent external peer review for every draft IRIS assessment that is part of our standard process, are second to none in the federal government and the scientific community. We find nothing in the NAS report that questions the integrity or quality of EPA's peer review through its Scientific Advisory Board or the independent contract peer reviews that EPA conducts on many of its assessments. We are confident that we can assure an independent peer review of any chemical assessments developed by the IRIS program.

Misc ques posed by David B:

Q: Is it clear the NAS disagreed with the bottomline conclusions of the formaldehyde assessment?

Deliberative Process / Ex. 5

Kacee Deener, MPH

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Date: 06/02/2011 05:45 PM
Subject: Re: IRIS press interview briefing

Audrey -

I have some comments on the Qs/As, see below in blue. Others feel free to weigh in. We can use the final product for future statements on IRIS.

From: Audrey Hoffer/DC/USEPA/US
To: Becki Clark/DC/USEPA/US@EPA
Cc: Vincent Cogliano/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA
Date: 06/02/2011 03:48 PM
Subject: IRIS press interview briefing
Sent by: Elizabeth Erwin

Publication
Pesticide & Chemical Policy
This is a 20-24 page trade press newsletter published weekly and available by subscription only. The editor says subscribers include most major chemical and pesticide manufacturers and their related trade associations, a number of major consumer food and product companies, major D.C.-based law firms that focus on pesticide and chemical issues and international and federal government agencies. According to editor, "we present arguments and look at the bigger implications of issues." Parent company is Informa, Inc, a publishing company that owns a variety of issue publications. OEA has dealt with the publication a few times and hasn't had problems with misquotes or misinformation.

Reporter
Jonathan(called J.R. by colleagues) *Pegg* --environmental reporter working for this publication for 5 years. He hasn't conducted an interview with ORD in the past. Most of his EPA interviews are with the pesticide office.

When
Fri June 3 @ 4:00. Reporter asked for 15 mins but I think you should plan to be on the phone a little longer, ~ 20--25 mins.

Location and format
Your office.
OEA staffer, *Mollie Lemon*, will call your phone and then loop in reporter.

Others attending
Vince, Audrey, and Liz will come to your office.

Background

- 4 weeks ago this reporter requested an interview with Vince to talk about the "ongoing efforts to reform the IRIS process, specifically the steps outlined by the Agency in 2009, and get his take on some criticisms of the program put forth by industry stakeholders and environmental groups."
- NCEA declined this interview pending release of our own press statement on IRIS.
- We drafted such a statement and it was stopped by Liz B who said it needed to be tied to the formaldehyde assessment; or, we could re-solicit the interview with Pesticide & Chemical Policy as the vehicle to get out our IRIS message.
- This interview is the result of your decision to seek an interview.

Below is a synthesis of talking points about the IRIS process, as answers to questions the reporter sent in (Vince contributed substantially to these); in excerpts from the Vitter/Inhofe letter; and, as misc points.

Advance questions from reporter and suggested answers:

Q: How is OMB now involved in the IRIS process?

Deliberative Process / Ex. 5

Q:EPA announced updates to the IRIS process in May 2009 – what major changes to the program have been made since then? How has the process been streamlined and improved? Is the IRIS process now fully in EPA's hands? Why is this more effective? Has the agency had time to address the concerns raised in the April NAS report on EPA's formaldehyde assessment?

Deliberative Process / Ex. 5

Q: That report prompted some industry stakeholders — notably the American Chemistry Council — and Sens. Inhofe and Vitter to criticize the transparency of the IRIS process. In an April letter from ACC chief Cal Dooley, the organization called on EPA to do more to discuss science as it reviews scientific information about how chemicals affect the body and more clearly explain why it relied on some scientific evidence more than others to reach conclusions about how the effects occurred.

Deliberative Process / Ex. 5

Q: What is the agency's response to ACC's concerns and to its request the agency submit all draft IRIS assessments to the National Academies in 2011 and 2012?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Q: Has EPA agreed to temporarily halt current reviews of acrylonitrile, methanol, MTBE, ETBE and styrene as requested by the senators? Why/why not?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Q: What about concerns the IRIS process is too slow — what is reasonable amount of time for an assessment to be completed? Is the agency concerned about the large backlog of chemicals awaiting evaluation?

Deliberative Process / Ex. 5

Q: How is EPA trying to streamline the process for assessing chemicals and planning to analyze substances that might present future risks?

Deliberative Process / Ex. 5

Q: Has EPA begun trying to revamp the process to evaluate exposure to multiple chemicals?

Deliberative Process / Ex. 5

Q: Has the agency begun to consider assessing nanomaterials through IRIS? What new challenges might that pose for the agency?

A: There is presently insufficient conventional data. We believe nanomaterials are more appropriate for NexGen approval.

Excerpts from Vitter/Inhofe letter:

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Misc ques posed by David B:

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Deliberative Process / Ex. 5

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